

REMARKS

FORMAL MATTERS:

Claims 1, 2, 4, 5, 8-10, 12-14, 17-19, 21-24, 27 and 28 are pending after entry of the amendments set forth herein.

Claims 3, 6, 7, 11, 15, 16, 20, 25 and 26 are canceled without prejudice.

Claims 1, 9, 17-19, and 21 are amended.

Applicants respectfully request the entry of amendments to claim 1 and believe that such amendments are proper under 37 C.F.R. §1.116. Specifically, the amendments to claim 1 incorporate limitations contained within previously pending now canceled claims. Specifically, claim 1 has been amended to incorporate limitations contained within previously pending now cancelled claims 3, 6 and 15.

The other claims amendments are formal in nature. Specifically, claims 9, 17-19 and 21 have been amended to change their dependency in view of the cancellation of other claims. No new matter has been added.

Response in General

The amendments to claim 1 overcome the 35 U.S.C. §102 rejections by incorporating limitations contained within previously pending now canceled dependent claims into claim 1. It is applicants' position that it would not be obvious to combine the references in the manner suggested within the rejection. The reason the references would not be combined is that none of the references alone or in combination recognize that the combination of a cationic aminoglycoside in an aqueous formulation at physiological pH will reduce the physical volume of a DNA sequence in an amount of about 10^3 to 10^6 relative to the original volume. This enormous reduction in volume is critical in terms of making it possible to create an aerosol wherein the aerosolized particles have a sufficiently small size so as to be delivered to the lungs of a human patient.

The mere existence in the prior art of individual features of the claimed invention does not, without more, render those claims obvious within the meaning of 35 U.S.C. §103. There must be positive evidence that the bringing together of such features would have been obvious to one of an ordinarily skilled person. Here, the references are completely lacking in an understanding of the dramatic effect on volume reduction that the cationic aminoglycoside has on DNA sequences.

Accordingly, the overall effect on particle size in an aerosolized formulation is not understood and the aerosol claimed by applicants is not disclosed or described within the references as taken alone or in combination with each other. Because this effect is not understood those skilled in the art would not be led towards creating such an aerosol in the absence of applicants' teachings.

To the extent that the Examiner requires a more detailed response with respect to the rejections such is provided below.

35 U.S.C. §102 Rejection

Claims 1, 2, 4, 5, 8, 10-12, 15-20, 25 and 26 were rejected under 35 U.S.C. §102 as anticipated by Wang et al.

Applicants point out that the rejection was not applied against previously pending now canceled claims 3 or 6. Accordingly, the rejection appeared to recognize that these features were not specifically disclosed within Wang et al. For example, the rejection recognizes that the Wang et al. publication does not disclose an aerosol wherein the aerodynamic diameter of the particles is in a range of about 0.5 micrometer to about 12 micrometers. This limitation was contained within previously pending now canceled claim 6 and is now included within amended claim 1. In view of such the 35 U.S.C. §102 rejection is believed to have been overcome.

Rejection under 35 U.S.C. §103 Wang et al. in view of Unger et al.

Claims 1, 2, 4, 5, 8, 10-12, 15-20, 25 and 26 were rejected under 35 U.S.C. §103 as obvious over the combination of Wang et al. with Unger et al. The rejection is traversed as applied and as it might be applied against the presently pending claims.

The rejection has apparently cited Unger et al. for its disclosure of plasmids and phagemids as well as cosmids. However, this rejection was not applied against dependent claims 3 and 6 in that the limitations of claims 3 and 6 are now included within independent claim 1. The rejection is believed to have been overcome.

Claims 6, 9, 21, 22, 27 and 28 were rejected as obvious over a combination of Wang et al., Unger et al. and further in view of Gonda et al. The rejection is traversed as applied and as it might be applied to the presently pending claims. The rejection was not applied against previously pending now canceled claim 3.

Claims 1-5, 8 and 10-26 were rejected as obvious over a combination of Gautam et al. in view of Douthart (1983), Douthart (1982) and Dubensky et al.

Claims 1-5, 8 and 10-26 were rejected over a combination of Gautam et al. in view of Douthart (1983), Douthart (1982), Dubensky and Unger et al.

Lastly, claims 6, 9, 27 and 28 were rejected as obvious over a combination of Gautam et al., Douthart (1983), Douthart (1982), Dubensky and Unger further in view of Gonda et al.

The rejections are traversed as applied and as they might be applied against the presently pending claims. First, it is applicants position that it would not obvious to combine these references in the manner suggested within the rejection in order to obtain applicants' invention. The references have been combined together only by utilizing the hindsight provided by applicants' teachings.

Applicants recognize that Wang et al. do refer to a number of different types of delivery systems such as at page 14, lines 10-22. Further, applicants recognize that Wang et al. referred to an aerosol inhaled into the lungs at page 15, lines 11-14. However, Wang et al. is not a disclosure which is directed toward aerosolized delivery. There is no appreciate with respect to the various parameters necessary in order to obtain an aerosol for inhalation by a human patient.

Neither Wang et al. as taken alone or in combination with the other cited references appreciate that a cationic aminoglycoside can be combined in a formulation with water and a DNA sequence at physiological pH and reduce the physical volume of the DNA by an amount in the range of about 10^3 to about 10^6 . This is important in forming an aerosol of a particular particle size such as a particle size in the range of 0.5 micrometer to about 12 micrometers (as claimed) which is necessary in order to provide for the desired efficiency in delivery of an aerosol to the lungs of a human patient.

CONCLUSION

Claim 1 has been amended to incorporate limitations contained within previously pending now cancelled claims. The entry of this amendment is respectfully requested. Many of the rejections are overcome by these amendments which were not applied against the previously pending now canceled dependent claims. In order to combine the references it is necessary to understand why it would be important to formulate a cationic aminoglycoside in a formulation of water in a DNA sequence to produce an aerosol. The importance of making this combination has been recognized by applicants wherein the cationic aminoglycoside causes a reduction in physical volume of about 10^3 to about 10^6 the original volume of the DNA sequence. This is important in terms of obtaining an aerosol of the desired

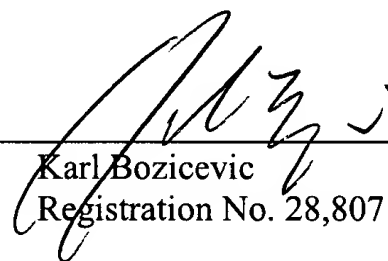
particle size range. However, the primary reference to Wang et al. does not describe particle size and does not recognize the effect of the cationic aminoglycoside on the DNA sequence in terms of changing its physical volume. In absence of the recognition of such it would not be obvious to combine the references in the manner suggested within the rejection in order to obtain applicants' invention. In view of such reconsideration and withdrawal of the rejections and allowance of the application is respectfully requested.

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number AERX-088.

Respectfully submitted,
BOZICEVIC, FIELD & FRANCIS LLP

Date: 23/June/04

By: 
Karl Bozicevic
Registration No. 28,807

BOZICEVIC, FIELD & FRANCIS LLP
200 Middlefield Road, Suite 200
Menlo Park, CA 94025
Telephone: (650) 327-3400
Direct: (650) 833-7735
Facsimile: (650) 327-3231

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